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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,354	06/30/2004	Masayo Higashiyama	2004_1016A	2612

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EXAMINER	
FRAZIER, BARBARA S	
ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
04/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/500,354	HIGASHIYAMA, MASAYO	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-10, 12, and 13 are pending in this application. Claim 11 stands canceled.

2. Addition of new claims 12 and 13 is acknowledged.

3. Claims 1-10, 12, and 13 are examined.

Claim Rejections - 35 USC § 112

4. The rejection of claims 1-10 under 35 U.S.C. 112, first paragraph is withdrawn in view of Applicant's amendment to claim 1.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. The previous rejection of claims 1-10 under 35 U.S.C. 103(a) as being unpatentable over Kita et (US Patent 6,307,052), Stevenson (US Patent 4,053,628) is modified as follows:

7. Claims 1-10, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevenson (US Patent 4,053,628) in view of Kita et al (US Patent 6,307,052).

The claimed invention is drawn to an aqueous liquid preparation comprising, in an aqueous solution, (+)-(S)-4-[4-[(4-chlorophenyl)(2-pyridyl)methoxy]piperidino]butyric acid (i.e., bepotastine) or a pharmacologically acceptable acid addition salt thereof, and a water-soluble metal chloride in a light-stabilizing effective amount of 0.2 w/v% or more (see claim 1).

Stevenson et al teach substantially clear, sterile aqueous solutions indicated for the treatment of conditions of the eye and the nose (abstract). The compositions may contain conventional excipients, such as sodium chloride (col. 2, lines 61-62) in amounts preferably less than 5% w/v (col. 3, lines 4-6); amounts of sodium chloride of 0.56% w/v and 0.42% w/v are exemplified (col.s 5 and 6, Examples 1 and 3). The compositions may also contain additional therapeutically useful compounds, such as antihistamine (col. 3, lines 7-13).

Stevenson et al do not specifically teach that the antihistamine may be bepotastine.

Kita et al teach that the benzenesulfonic acid salt or benzoic acid salt of (S)-4-[4-[(4-chlorophenyl)(2-pyridyl)methoxy]piperidino]butanoic acid (i.e., bepotastine) is excellent in antihistaminic activity and antiallergic activity, has little hygroscopicity and excellent in physicochemical stability, so that it is particularly suitable compound as a medicine (col. 1, lines 10-22).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to select bepotastine as the antihistamine in the composition of Stevenson et al; thus arriving at the claimed invention. One skilled in the art would be

motivated to do so, with a reasonable expectation of success, because bepotastine provides the benefits of having excellent antihistaminic activity, little hygroscopicity, and excellent physicochemical stability, as taught by Kita et al.

Regarding the limitations, "a water-soluble metal chloride in a light-stabilizing effective amount of 0.2 w/v% or more" (claim 1), "sodium chloride at not less than 0.2 w/v% and not more than 0.8 w/v% in a light-stabilizing effective amount" (claim 10), and "light-stabilized with a water-soluble metal chloride at not less than 0.2 w/v% (claim 13), Stevenson et al exemplify amounts of sodium chloride of 0.56% w/v and 0.42% w/v (col.s 5 and 6, Examples 1 and 3). These amounts would necessarily be a light-stabilizing effective amount, as evidenced by Applicant's specification. Since concentrations of sodium chloride of 0.56% and 0.42%, as taught by the Stevenson et al, overlaps with the amount of sodium chloride disclosed by applicant as being a "light-stabilizing effective amount (specification, page 8, lines 6-15, including Table 1), one would reasonably expect that the sodium chloride component of the aqueous liquid preparations encompassed by the prior art, wherein said sodium chloride is present in an amount of 0.2% or more (e.g. 0.56%) would also be a light-stabilizing effective amount, absent objective evidence to the contrary.

Regarding claims 2, 3, and 12, Stevenson et al exemplify sodium chloride as an excipient present in the composition, in amounts of 0.56% w/v and 0.42% w/v (col.s 5 and 6, Examples 1 and 3), which are within Applicant's range.

Regarding claim 4, Stevenson et al teach that amounts of additional compounds may be present at a concentration of from about 0.05 to 0.6% w/v (col. 3, lines 32-34).

This range overlaps that of the claimed invention, and one skilled in the art would be motivated to manipulate the amount of antihistamine present in the composition from within said ranges by routine experimentation, in order to optimize antihistaminic activity of the resultant composition.

Regarding claims 5 and 6, Kita et al teach the benzenesulfonic acid salt of bepotastine (col. 1, lines 11-13).

Regarding claim 7, Stevenson et al teach that the preferred pH for maximum stability is from 4 to 7.5 (col. 3, lines 2-4), which is comparable to Applicant's range.

Regarding claims 8 and 9, Stevenson et al teach that the composition may be administered to the eye or the nose, and exemplify eye drops and nasal spray (Examples 1-3). Since a "nasal spray" is comprised of droplets when sprayed into the nose, it reasonably reads on "nasal drop".

Response to Arguments and Declaration

8. Applicant's arguments filed 10/8/09 have been fully considered but they are not persuasive.

In response to Applicant's arguments regarding differences between the antihistamine compounds exemplified in Stevenson et al and the antihistamine taught by Kita et al (i.e., bepotastine), it is noted that all of the compounds taught fall within the class of antihistamines, and therefore are functionally equivalent to one another. Furthermore, Stevenson et al do not limit their invention to the antihistamines named, but rather teach that antihistamines may be added, and only teach Antazoline or

diphenhydramine as examples. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Additionally, one skilled in the art would be motivated to select bepotastine as the antihistamine, due to its excellent activity as an antihistamine as well as its stability, as taught by Kita et al.

In response to Applicant's arguments regarding the light instability problem associated with bepotastine, it is noted that the presence of sodium chloride in the compositions of Stevenson et al is already exemplified (Examples 1 and 3), in light-stabilizing effective amounts, and therefore the sodium chloride of the composition of Stevenson et al would necessarily provide a light-stabilizing effect to the added components, including antihistamines.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure *at the time of invention*, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to Applicant's arguments regarding the Declaration, it is noted that the Declaration has been considered but is not deemed persuasive for overcoming the rejection because the light-stabilizing effective amounts of sodium chloride are exemplified in Stevenson et al, and thus the sodium chloride of the composition of Stevenson et al would necessarily provide a light-stabilizing effect to the added components, including antihistamines, for reasons stated above.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF
/Ashwin Mehta/
Primary Examiner, Technology Center 1600